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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,925	01/09/2001	Christian Quellet	12846/121488	6779

7590 11/19/2003
Mark E. Waddell, Esq.
Bryan Cave LLP
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New York, NY 10167-0034

EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/19/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/756,925

Applicant(s)

QUELLET ET AL.

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction requirement as indicated in the Office action dated December 18, 2002 is withdrawn pursuant to the July 24, 2003 decision on applicants' petition under 37 C.F.R. 1.144, filed May 2, 2003.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 2-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuei et al. (US 5589194) ("Tsuei") in view of Carr (US 5183690) and further in view of Carr et al. and Lee et al. (EP 0480729 A1) ("Lee").

Tsuei teaches microcapsules having water-soluble or insoluble active components dissolved or dispersed, respectively, in solid thermoplastic matrix. See abstract; col. 3, line 21 – col. 4, line 67. See also Example 7, teaching microcapsules containing beta-carotene in vegetable oil. The reference also teaches that the amount of the active components and size of the microcapsule can be controlled by the prior art process. See col. 3, lines 27 – 39. The reference also teaches the method of making microcapsules via extrusion process. See col. 3, line 64- col. 4, line 7. See instant claims 11-13.

Tsuei fails to specifically teach the size of the microcapsules. The reference also fails to teach starch matrix.

Carr teaches encapsulated biologically active agents in a starch matrix. See abstract. The reference teaches that it is well known in the art to employ natural or modified starch for water-insoluble materials. See col. 1, lines 36-42; col. 3, lines 15 – 22; col. 5, lines 3 – 28. Carr also teaches that core materials “dissolved, emulsified, or otherwise dispersed in solvents or carriers” are encapsulated. See col. 3, lines 36-43, suggesting that liquid actives in emulsion form are obvious. The biological actives suitable for the invention include flavor composition, odor composition, vitamin, and bactericide. See col. 3, lines 23-36. See instant claims 6-9.

Carr fails to teach the size of the microcapsule as recited by the instant claims.

Lee discloses method of microencapsulating oil droplet containing drugs for oral administration using polysaccharide as a capsule material. See abstract. The reference teaches mixing the drug with liquid oil and producing an oil-in-water emulsion containing the drug-dispersed oil droplets of 1-5 microns. The reference also teaches that the final product is in powdery state. See Example 1. The reference teaches using the drug in the amount of 1-40 % of the liquid oil. See instant claims 4-5. See also p. 3, lines 25 – p. 4, line 24 for the weight amounts of chelating agent, emulsifier, and the capsule material.

While the reference fails to teach the size of the microcapsules per se, given that the size of the droplet is within 1-5 microns, examiner takes the position that the prior art microcapsules are within the obvious range of the claimed limitation, absent evidence to the contrary.

Examiner notes that claims 28 is a product by process claim. It is well known in patent law that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, claim 28 is rejected here because the recited method is not give patentable weight, and the powdery microencapsulated composition meets the limitation of the recited composite material.

For claim 10, it is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. See In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). As shown by the recited teaching, the instant claims define nothing more than the concomitant use of two biological actives for controlled-release. It would follow that the recited claims define prima facie obvious subject matter.

Given the general teaching of controlling the size of microcapsules by techniques known in the art, as taught in Tsuei, it would have been obvious to one having ordinary skill in the art at the time of the invention to have looked to the prior arts such as Lee and produced the microcapsules having size of 1-5 microns.

2. Claims 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuei, Carr, and Lee as applied to claims 2-10 and 28-37 above, and further in view of Bilbrey (US 5290547).

Tsuei, Carr, and Lee fail to teach using the surfactants and the amount of the components as recited in the instant claims.

Bilbrey teaches odor-masking products comprising coated oil-in-water emulsion droplets of fragrance oil for the use odor masking products. See abstract; col. 1, line 61 – col. 2, line 55. The reference teaches that the size of the droplets is in the range of 2-300 μm . See col. 3, lines 11 – 26. Adding emulsifiers such as sodium lauryl sulphate, sorbitan tristearate, sorbitan trioleate or sorbitan monooleate for surfactants is disclosed in col. 4, lines 54 – 65. The amount of actives, water, surfactant, and additives in microemulsion is disclosed in col. 5, lines 29-41.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composite materials of the combined references by adding the surfactants and components as suggested by Bilbrey, because of the expectation of successfully producing a uniform dispersion of active ingredients in the composite materials.

Response to Arguments

Applicant's arguments filed on July 7, 2003 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

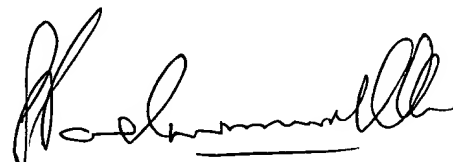
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
November 17, 2003



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

11/17/03